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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

UNITED STATES OF AMERICA, Plaintiff, v. KUN WO FOOD PRODUCTS, INC., a corporation, and ZI XING LIU and ZI CHEN LIU, individuals, Defendants.	Civil No. __16-1927_____ COMPLAINT FOR INJUNCTION

Plaintiff, the United States of America, by its undersigned counsel, and on behalf of the United States Food and Drug Administration ("FDA"), respectfully represents to this Court as follows:

COMPLAINT FOR PERMANENT INJUNCTION

1. This statutory injunction action is brought under the Federal Food, Drug, and Cosmetic Act (the "Act"), 21 U.S.C. § 332(a), to enjoin and restrain Kun Wo Food Products, Inc., a corporation, and Zi Xing Liu and Zi Chen Liu, individuals (collectively, "Defendants") from violating 21 U.S.C. § 331(k), by causing articles of food that are held for sale after shipment of one or more components in interstate commerce to become adulterated within the meaning of 21 U.S.C. § 342(a)(4).

JURISDICTION AND VENUE

2. This Court has jurisdiction over the subject matter and all parties to this action under 28 U.S.C. §§ 1331, 1337, and 1345, and 21 U.S.C. § 332(a).

3. Venue in this district is proper under 28 U.S.C. §§ 1391(b) and (c).

INTRADISTRICT ASSIGNMENT

4. The conduct alleged in this Complaint occurred within San Francisco County.

DEFENDANTS

5. Defendant Kun Wo Food Products, Inc., ("Kun Wo"), is a California corporation with its principal place of business at 2939 16th Street, San Francisco, California 94103, within the jurisdiction of this Court. Kun Wo produced, processed, packed, held, and distributed rice noodles.

6. Defendant Zi Xing Liu, who also uses the name David Z. Liu, is a co-owner of Kun Wo. Mr. Zi Xing Liu is the most responsible person at the firm. He has ultimate authority over all of the firm's operations, including financial expenditures, production processes, and employee supervision. Defendant Zi Xing Liu performed his duties at 2939 16th Street, San Francisco, California 94103, within the jurisdiction of this Court.

7. Defendant Zi Cheng Liu is a co-owner of Kun Wo. Mr. Zi Chen Liu shares responsibility with Defendant Zi Xing Liu for the firm's production processes. He is also responsible for product distribution. Defendant Zi Chen Liu performed his duties at 2939 16th Street, San Francisco, California 94103, within the jurisdiction of this Court.

8. Defendants were engaged in preparing, processing, packing, holding, and distributing articles of food, including ready-to-eat rice noodles.

9. Defendants' rice noodles were processed from ingredients, including rice, which were shipped from locations outside the state of California, including Arkansas. Defendants distributed their products within the state of California, to local customers in the San Francisco area.

DEFENDANTS' VIOLATIONS OF THE ACT

10. Defendants violate the Act, 21 U.S.C. § 331(k), by causing food to become adulterated while it is held for sale after shipment of one or more of its components in interstate commerce.

11. Food is adulterated with the meaning of the Act if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. 21 U.S.C. § 342(a)(4).

12. Food processors must adhere to the current good manufacturing practices ("cGMP") provided by FDA regulations. 21 C.F.R. pt. 110. The cGMP standards are applied in determining whether food is adulterated under the Act. 21 C.F.R. § 110.5(a).

13. Defendants' rice noodles have been manufactured and distributed at room temperature and intended to be consumed with little or no further processing. Thus, the manner

in which Defendants prepare, pack, hold, and distribute their rice noodles is crucial to minimize the potential for bacterial contamination and reduce the risk of illness to consumers.

14. FDA inspections at Defendants' facility establish that Defendants repeatedly violated the Act by failing to adhere to cGMP, preparing, packing, and holding rice noodles under insanitary conditions whereby the noodles may have become contaminated with filth or may have been rendered injurious to health, and failed to take corrective actions to come into compliance, despite notification of their deficiencies by the FDA.

15. Defendants' rice noodles are at risk of contamination by several types of disease-causing bacteria including *Listeria monocytogenes ("L. mono"), Bacillus cereus ("B. cereus"), Salmonella, Echerichia coli ("E. coli"), and Staphylococcus aureus ("S. aureus").*

16. Defendants' rice noodles are adulterated within the meaning of 21 U.S.C. § 342(a)(4), and Defendants' violations are likely to recur absent court action.

FDA INSPECTIONS

17. FDA conducted its most recent inspection of Defendants' facility on January 20-21, and February 4, 2016 ("the 2016 inspection"). This inspection followed a previous violative inspection in September and October 2015 ("the 2015 inspection").

18. The 2016 inspection documented significant evidence of Defendants' failure to follow cGMP, practices that cause food to be at risk of bacterial contamination, and Defendants' failure to correct violations found in the 2015 inspection, including but not limited to the following:

(a) Defendants failed to take all necessary precautions to prevent food handlers from contaminating food with microorganisms or foreign material, as required by 21 C.F.R. § 110.10(b)(9). For example, an employee used the vat containing rice soaking for the day's

production to rinse her bare hands after handling equipment and touching her face and hair. Employees also touched packing boxes, electrical switches, a fuse box, buckets, carts, and machinery, all of which were soiled, and then touched rice noodles without sanitizing or changing their gloves;

(b) Defendants failed to take all reasonable precautions throughout food manufacturing operations to ensure that production procedures do not contribute contamination from any source, as required by 21 C.F.R. § 110.80. For example, condensate dripped from a hose suspended from the ceiling into the vat containing soaking rice and from a copper pipe with a green and black film on its surface into a grinder containing rice for processing;

(c) Defendants failed to handle and maintain equipment, containers, and utensils used to convey, hold, or store food in a manner that protects food from contamination, as required by 21 C.F.R. § 110.80(b)(7). For example, the machines used to steam, cool, slice, and weigh the rice noodles were covered in grease and grime. FDA investigators observed that the first sheets of rice noodles coming off the production machine contained particulate matter. Additionally, a black mold-like substance was observed on the mesh surface of colanders used to scoop rice from the soaking vat;

(d) Defendants failed to take effective measures to exclude pests from processing areas and protect against contamination of food by pests, as required by 21 C.F.R. § 110.35(c). For example, the top and bottom of the front door and back screen door of the facility had gaps that were large enough to permit pests to enter the premises and access the raw-material storage area and the food-processing area, and raw ingredients and recycled boxes were stored in the front of the facility in a disorganized, cluttered manner that may attract and harbor pests;

(e) Defendants failed to hold food in a manner to prevent its contamination with

bacteria, as required by 21 C.F.R. § 110.8(b)(3), by maintaining its finished rice noodles at room temperature for many hours;

(f) Defendants failed to maintain buildings, fixtures, and other physical facilities in a sanitary condition, and failed to clean equipment in a manner that prevents contamination of food and food-contact surfaces, as required by 21 C.F.R. § 110.35(a). For example, employees used a hose to spray the floor and machinery with water that splashed around the soaking vat and grinders and near processing tables. Water pooled on the floor and remained wet after cleaning was completed. The uneven floor tiles near the vat, grinders, and mixer, used to process the rice and other ingredients into rice slurry, also caused water to pool and prevented it from draining. Uncovered food was stored in close proximity to locations where water pooled and splashed; and

(g) Defendants failed to minimize the potential for contamination of food and food-contact surfaces when operating fans, as required by 21 C.F.R. § 110.20(b)(6). For example, sheets of rice noodles were cooled by fans covered in dirt and debris that blew air directly on the food.

19. FDA documented the same or similar violations during the 2015 inspection, including, but not limited to:

(a) employees using the vat containing soaking rice to rinse their bare hands, rags, and buckets after using the rags and buckets to clean the production area with detergent, and employees touching dirty equipment and then using their bare, unwashed hands to grab rice noodles for packaging;

(b) condensate dripping off a hose, covered in dirt and black residue, onto the rim of an uncovered grinder filled with an in-process rice slurry;

(c) employees submerging soiled buckets from the floor into the vat of soaking rice to fill them with water, which was then splashed onto the floor within one foot of trays of finished product;

(d) cockroaches and fruit flies in the food processing area and a rodent in the area where raw ingredients were stored;

(e) the conveyor belts on a machine used to steam, cool, and slice rice noodles covered with a build-up of brown residue and the first sheets of rice noodles coming off the machine containing particulate matter;

(f) finished, cut rice noodles held in buckets with dirt on their outsides and built-up grease on their rims. Employees packaged the rice noodles that touched the soiled rims and outsides of the buckets, as well as noodles that came off the slicing machine's soiled conveyor belt, missed the buckets, and landed on a tray underneath the equipment;

(g) an employee using a soiled hose from the floor to flush rice slurry from the grinder and from the mixer hose, which transports the slurry from the grinder to the mixer; and

(h) sheets of rice noodles being cooled by fans covered in dirt and debris that blew air directly on the food.

20. During the 2015 inspection, FDA investigators swabbed various surfaces in Defendants' production area, including the buckets used during processing. FDA's analyses of these samples revealed the presence of bacterial contamination at the facility. *L. mono* was identified on the exterior of one bucket, and *L. seeligeri* was found on the exterior of another bucket. *L.mono* is the bacterium that causes the disease listeriosis. The most serious forms of listeriosis can cause meningitis and septicemia. *L. seeligeri* does not cause disease; however, it is a marker indicating that conditions are favorable for the survival and growth of *L. mono*. FDA

investigators noted during the 2015 inspection that Defendants' employees routinely submerged these buckets in the water that contained soaking rice. *L. mono* was found elsewhere in the environment, for example, on a brick supporting one corner of the soaking vat, on a drain, and on a cracked floor tile. Defendants' employees splashed or sprayed water on or near these areas, which were in close proximity to uncovered food.

NOTIFICATIONS OF NON-COMPLIANCE

21. At the close of the 2015 and 2016 inspections, FDA investigators provided a List of Inspectional Observations ("Form FDA-483") to Defendants enumerating the observed violations. An investigator also discussed the violations in Cantonese with Defendants to ensure that they understood the deficiencies and the importance of corrections.

22. FDA also notified Defendant Zi Xing (David) Liu of the positive *L. mono* test results by telephone on October 29, 2015.

23. In response to the 2015 inspection, Defendants made a number of inadequate and unsuccessful corrections. Defendants replaced plastic buckets used for packing rice noodles and fans that cooled sheets of rice noodles, and removed the plastic bins of dirty rags that were stored above uncovered finished product. Defendants also promised to institute policies to improve employees' practices, including posting signs that the water in the vat used for soaking rice should not be used to rinse employees' hands, buckets, rags, or sponges. However, the 2016 inspection revealed that the new buckets and fans had not been kept clean, and that employee practices had not improved.

24. Despite FDA's efforts and warnings, and the Defendants' promises to correct violations, Defendants have failed to comply with cGMP and implement controls that are

adequate to protect their food from the risk of contamination with filth and disease-causing bacteria.

25. Based on the foregoing, there is a reasonable likelihood that, unless restrained by order of this Court, Defendants' violations will continue in the manner set forth above.

WHEREFORE, the Unite States respectfully requests that the Court:

I. Order that Defendants, and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, and assigns, and any and all persons in active concert or participation with any of them (including individuals, partnerships, corporations, subsidiaries, and affiliates), are permanently restrained and enjoined under 21 U.S.C. § 332(a) from directly or indirectly violating 21 U.S.C. § 331(k), by causing articles of food that are held for sale after shipment of one or more components in interstate commerce to become adulterated within the meaning of 21 U.S.C. § 342(a)(4);

II. Order that Defendants, and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, and assigns, and any and all persons in active concert or participation with any of them (including individuals, partnerships, corporations, subsidiaries, and affiliates), cease, directly or indirectly, receiving, preparing, processing, packing, labeling, holding, or distributing articles of food unless and until Defendants bring their receiving, preparing, processing, packing, labeling, holding, and distribution operations into compliance with the Act and implementing regulations, to FDA's satisfaction;

III. Order that FDA be authorized pursuant to this injunction to inspect Defendants' place(s) of business and all records relating to the receiving, preparing, processing, packing, labeling, holding, and distribution of food to ensure continuing compliance with the terms of the

injunction, the costs of such inspections to be borne by Defendants at the rates prevailing at the time the inspections are accomplished; and

IV. Award the United States its costs incurred in pursuing this action, including the costs of investigation to date, and such other relief as the Court deems just and proper.

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DATED this 12th day of April, 2016.

Respectfully submitted,

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